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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/004,395	01/08/1998	ROBERT D. GILMORE JR.	97,429	1172

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EXAMINER	
MINNIFIELD, NITA M	
ART UNIT	**PAPER NUMBER**
1645	33

DATE MAILED: 09/04/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/004,395	GILMORE ET AL	
	Examiner	Art Unit	
	N. M. Minnifield	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)[·] Responsive to communication(s) filed on *01 July 2002* .

2a)[·] This action is **FINAL**. 2b)[ ] This action is non-final.

3)[ ] Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)[·] Claim(s) *14-17,20-26,28 and 29* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)[ ] Claim(s) _____ is/are allowed.

6)[·] Claim(s) *14,16,20,24 and 26* is/are rejected.

7)[·] Claim(s) *15,17,21-23,25,28 and 29* is/are objected to.

8)[ ] Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)[ ] The specification is objected to by the Examiner.

10)[ ] The drawing(s) filed on _____ is/are: a)[ ] accepted or b)[ ] objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)[ ] The proposed drawing correction filed on _____ is: a)[ ] approved b)[ ] disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)[ ] The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)[ ] Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)[ ] All b)[ ] Some * c)[ ] None of:

1.[ ] Certified copies of the priority documents have been received.

2.[ ] Certified copies of the priority documents have been received in Application No. _____ .

3.[ ] Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)[ ] [illegible]

Attachment(s)

1)[ ] Notice of References Cited (PTO-892)

2)[ ] Notice of Draftsperson's Patent Drawing Review (PTO-948)

3)[ ] [illegible]

4)[ ] Interview Summary (PTO-413) Paper No(s).

5)[ ] Notice of Informal Patent Application (PTO-152)

6)[ ] [illegible]

DETAILED ACTION

Response to Amendment

1. Applicants' Response to Office Action filed July 1, 2002 is acknowledged and has been entered. Claims 14-17, 20-26, 28 and 29 are now pending in the present application. All rejections have been withdrawn in view of Applicants' arguments in the response, with the exception of those discussed below.

2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

3. Claims 14, 16, 20, 24 and 26 are rejected under 35 U.S.C. 102(a) as being anticipated by Fikrig et al (WO 97/42325).

Fikrig et al disclose a P37 protein to be used in the diagnosis of Lyme disease (abstract; pages 7, 10, 11 and 14-15). Fikrig et al disclose the use of fusion proteins (abstract; p. 23). The prior art anticipates the claimed invention.

Applicant's arguments filed June 25, 2001 have been fully considered but they are not persuasive. Applicants have asserted that the P37 protein of Fikrig et al is not the same as the 37-kDa FlaA or P37 protein of the present invention. Applicants have asserted that the nucleic acid sequence (SEQ ID NO: 6) of Fikrig et al is not the same as the nucleic acid sequence (SEQ ID NO: 2) of the claimed invention. However, it is noted that the rejected claims (14, 16, 20, 24 and 26) do not recite DNA or amino acid sequences: only a FlaA protein which Applicants

diagnostic reagent

The rejection is maintained for the reasons of record. Applicant's arguments filed July 1, 2002 have been fully considered but they are not persuasive. The characteristics Applicants are relying on (i.e. function of the protein, molecular of the protein, source of the protein, amino acid sequence and nucleic acid sequence of the protein) are not set forth in the claims under rejection (claims 14, 16, 20, 24 and 26).

4. Claim 14 is rejected under 35 U.S.C. 102(b) as being anticipated by Grodzicki et al (1988), Hansen et al (1988), Johnson et al (1996), or Gassmann et al (1989).

Grodzicki et al discloses a flagellar protein from *Borrelia burgdorferi* (abstract). Grodzicki et al discloses that the flagellar antigen is superior to the sonicated whole spirochetes for early diagnosis of Lyme disease by ELISA (p. 790, col. 2; p. 794, col. 2).

Hansen et al discloses a flagellar protein from *Borrelia burgdorferi* that was used in diagnostic testing (abstract; p. 345, col. 2). Hansen et al discloses that the flagellar protein is easy to purify in sufficient quantity and is a suitable reference antigen for routine serodiagnosis of Lyme disease (abstract). Hansen et al discloses that the aim of the study was to develop a more sensitive serological assay using a single *Borrelia* antigen (p. 338, col. 1). Hansen et al discloses *B. burgdorferi* flagellum showed an early and strong immune response against the 41-kD band corresponding to flagellum (p. 338, col. 2; p. 344, col. 2). *B. burgdorferi*

and methods: ... the ELISA using the *B. burgdorferi* flagellum as a test antigen

significantly improves serodiagnosis of Lyme disease (p. 344, col. 1). "The use of a single purified antigen such as the *B. burgdorferi* flagellum, as the test antigen eliminates the detection of such unspecific antibodies." (p. 344, col. 2).

Johnson et al discloses a purified flagellar antigen from *Borrelia burgdorferi* (abstract) and suggest its use in diagnosis of Lyme disease (p. 346).

Gassmann et al discloses a 41 kDa flagellar protein from *Borrelia burgdorferi* that "...appears to an immunodominant antigen producing an early and strong response in most if not all individuals during infections in humans. It would represent a very good antigen for serodiagnosis of Lyme disease, if its crossreactivity with flagella of other bacteria was low." (abstract). Gassmann et al discloses that the entire flagellar protein or parts of it may represent appropriate antigens for specific serodiagnosis of *Borrelia burgdorferi* infections (p. 102).

The recitation of diagnostic reagent has not been given patentable weight because the recitation occurs in the preamble. A preamble is generally not accorded any patentable weight where it merely recites the purpose of a process or the intended use of a structure, and where the body of the claim does not depend on the preamble for completeness but, instead, the process steps or structural limitations are able to stand alone. See *In re Hirao*, 535 F.2d 67, 190 USPQ 15 (CCPA 1976) and *Kropa v. Robie*, 187 F.2d 150, 152, 88 USPQ 478, 481 (CCPA 1951).

The recitation of "recombinant" is viewed as a process limitation.

Intended use of the claimed invention must result in a structural difference

between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. In a claim drawn to a process of making, the intended use must result in a manipulative difference as compared to the prior art. See *In re Casey*, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963).

The rejection is maintained for the reasons of record. Applicant's arguments filed July 1, 2002 have been fully considered but they are not persuasive. The characteristics Applicants are relying on (i.e. function of the protein, molecular of the protein, source of the protein, amino acid sequence and nucleic acid sequence of the protein) are not set forth in the claim under rejection (claim 14).

5. Claims 14, 16, 20, 24 and 26 are rejected under 35 U.S.C. 102(a) as being anticipated by Fikrig et al 1997 (Immunity).

Fikrig et al discloses antigens, P37, from *Borrelia burgdorferi* for diagnosis of Lyme disease (abstract; p. 531, col. 2; p. 538). Fikrig et al discloses that P37 appears to be expressed in the early stages of mammalian infection (p. 534). Fikrig et al discloses methods of making P37 by recombinant means (using expression vectors, host cells, *E. coli*, etc) as well as making fusion proteins that comprise P37 and GT (p. 538).

arguments filed ... have been fully considered but they are not

persuasive. The characteristics Applicants are relying on (i.e. function of the protein, molecular of the protein, source of the protein, amino acid sequence and nucleic acid sequence of the protein) are not set forth in the claims under rejection (claims 14, 16, 20, 24 and 26).

6. Claims 15, 17, 21-23, 25, 28 and 29 are objected to because they depend from a rejected claim.

7. It is noted that claims 15, 17, 21-23, 25, 28 and 29 would be allowable if written in independent form and pending an interference sequence search.

8. No claims are allowed.

9. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to N. M. Minnifield whose telephone number is 703-305-3394. The examiner can normally be reached on M-F (8:00-5:30) Second Friday Off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette R.F. Smith can be reached on 703-308-3909. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4556 for regular communications and 703-308-4556 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

N. M. Minnifield
Primary Examiner
Art Unit 1645

nmm

August 30, 2002